K051639

AUG 2 - 2005

510(k) Summary

AS Software Inc.
AS-OBGYN Information System

The below summary is provided as part of this abbreviated Premarket Notification 510(k) in compliance with 21CFR807.92 Content and format of a 510(k) summary.

Name of Submitter:

AS Software, Inc.
80 South Woodland St.
Englewood, NJ 07631
(201) 541-1900
(201) 541-1199 Fax

Contact Person:

Kim A. Nathanson, Chief Operating Officer

Date of Summary:

June, 14 2005

Device Name:

AS-OBGYN Information System

Other Device Proprietary Name:

AS-EMR System

Common or Usual Names:

Common Name: Image Acquisition, Review and Reporting System
Classification name: Picture Archiving and Communications System

Substantial Equivalence:

Manufacturer	Device Name	510(k) Number	Clearance Date
Digisonics, Inc.	OB-View (Doctors Review System)	K970402	Mar. 26 1997
R4 Telemedicine Systems' Inc.	R4's Remote Fetal Medicine Ultrasound System	K000443	Apr. 24 2000
Vision Chips, Inc.	Observer Ultrasound Reporting and Imaging System	K022877	Feb. 5 2003

Device Description:

The AS-OBGYN Information System consists of robust and comprehensive patient information. The system allows the management of patient clinical data and image management (communication, review, storage and archiving). The system provides the capability to edit patient information and clinical data as well as the generation of electronic and printed reports. The device is available in a variety of configurations depending on specific requirements.

The AS-OBGYN Information System communicates with DICOM modalities devices. In the case of DICOM sessions the communication is handled through the AS-DICOM Server package (for TCP/IP connections). For non-DICOM sessions, the communication is handled through the AS-COMM package (for TCP/IP, RS-232 and USB connections). The AS-OBGYN Information System receives single and multi-frame images from devices over the network using the DICOM communication, while additional descriptive data may be received through DICOM session or non-DICOM sessions.

All the hardware used by AS-OBGYN Information System (including computers, storage drives, network interface, monitor and printer) is commercial off-the-shelf equipment.

Intended Use:

The AS-OBGYN Information System is intended to automate the management of patient information. The system allows image acquisition, review, document, storage, archive and reporting.

User Characteristics:
The AS-OBGYN Information System is intended for use by obstetricians, gynecologists, perinatologists, radiologists and cardiologists. The system is designed for use in hospitals and medical offices.

Comparison to Predicate Devices:

The AS-OBGYN Information System is substantially equivalent to the following legally marketed devices:

- Digisonics, Inc., OB-View (Doctors Review System)
- R4 Telemedicine Systems, Inc., R4's Remote Fetal Medicine Ultrasound System
- Vision Chips, Inc., Observer Ultrasound Reporting and Imaging System

Like all of the above devices, the AS-OBGYN Information System allows for the management of patient information, examination data and medical images. All these devices as well as the AS-OBGYN Information System run on Microsoft operating systems.

- The R4's Remote Fetal Medicine Ultrasound System also allows for a telemedicine sessions which the AS-OBGYN Information System does not.
- The R4's and Digisonics devices also exercise framegrabber digitizers, which the AS-OBGYN Information System does not.
- Like the R4's and the Vision Chips's Observer, the AS-OBGYN Information System includes calculations to convert fetal measurements to gestational ages.
- The main difference and advantage of the AS-OBGYN Information System over the other abovementioned devices is its powerful user interface and ease of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 - 2005

Ms. Kim A. Nathanson
Chief Operations Officer
AS Software, Inc.
80 South Woodland Street
ENGLEWOOD NJ 07631

Re: K051639
Trade/Device Name: AS-OBGYN Information System
Regulation Number: 21 CFR 892. 2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 14, 2005
Received: June 20, 2005

Dear Ms. Nathanson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K05 1639

Indications for Use Statement

Device Name:
AS-OBGYN Information System

Indications for Use:

The AS-OBGYN Information System is intended to automate the management of patient information. The system allows image acquisition, review, document, storage, archive and reporting.

The AS-OBGYN Information System is intended for use by obstetricians, gynecologists, perinatologists, radiologists and cardiologists. The system is designed for use in hospitals and medical offices.

Prescription Use ✓

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number